

Declaration of Compliance

Bindzil CC401

Bindzil CC401 is a neutral, aqueous dispersion of colloidal silica at a 37 % concentration. The silica sol is sterically stabilized and the amorphous silica particles carry a negative surface charge. The particles are discrete, have a smooth, spherical shape, and are present in a narrow particle size distribution. The particles have been surface modified with a reactive epoxy silane.

Bindzil CC401 is a translucent liquid, slightly more viscous than water.

Product Characteristics

SiO ₂ and silylated SiO ₂ :	37 % by weight
Ethanol:	2.5 % by weight
pH:	8.0
Viscosity:	8 cP
Density:	1.3 g/cm ³
Average particle size:	12 nm

When leaving the factory, **Bindzil CC401** has the following compliance status with the below mentioned regulations on food contact plastics, paper and board or other materials.

1.1 European Union and Member States

Silicon dioxide is listed as Ref. N. 86240 in *Annex III Section A (Incomplete list of additives fully harmonized at Community level)* of *Directive 2002/72/EC*, as amended by *Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC* and *Regulation (EC) No. 975/2009*, and replacing the old *Directive 90/128/EEC (as amended) relating to plastic materials and articles intended to come into contact with foodstuffs* without any restrictions.

Silicon dioxide, silanated is listed as Ref. N. 86285 in the same *Annex III Section A* of *Directive 2002/72/EC* and also without restrictions.

Ethanol is listed as Ref. N. 16780 in *Annex II Section A (List of authorized monomers and other starting substances)* and as Ref. N. 52800 in *Annex III Section A*, again without specific restrictions.

This means that **Bindzil CC401** is fully harmonized and approved for food contact plastics on EU level. The final material should be in compliance with the relevant European regulations (*Framework Regulation (EC) No. 1935/2004/EC, Directives 2002/72/EC, 82/711/EEC, 85/572/EEC*, as amended).

Silicon dioxide and **silicon dioxide, silanated** are furthermore mentioned on the *List 1 on Additives*, **ethanol** is listed on *Appendix A on Monomers*, in the *Technical Document No. 1* related to the *Council of Europe Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs* with the identical restrictions as mentioned for plastic applications.

Silicon dioxide and **silicon dioxide, silanated** are listed in the *Council of Europe Resolution AP (2004) 1 on coatings intended to come into contact with foodstuffs, Technical Document No. 1* on the *List 1 on Additives*, **ethanol** on the *List 1 on Monomers* with the identical restrictions as mentioned for plastic applications.

1.1.1 Austria

Directive 2005/79/EC adopted by *Kunststoff-Verordnung*, published in Bundesgesetzblatt II 452/2006.

1.1.2 Belgium

Directive 2005/79/EC adopted by *Royal Decree of 05.07.2006*.

1.1.3 Czechia

Directive 2005/79/EC adopted by *Vyhláska C. 551/2006*, which amends *Vyhláska C. 38/2001*.

1.1.4 Denmark

The *Fødevarestyrelsens Bekendtgørelse Nr. 167* af 03/03/2009 is the relevant regulation for all food contact materials and implements already the *EU Directive 2008/39/EC*.

1.1.5 Finland

Directive 2004/19/EC adopted by *Decree No. 181/2005* of 10.03.2005.

1.1.6 France

Directive 2008/39/EC adopted by *Arrêté du 19.11.2008 (JORF 07.12.2008)*.

Brochure N° 1227 :

Arrêté du 14 Septembre 1992 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boisson alimentaires, listed on Annexe, Capitre II, below PM/REF 86240 as "Dioxyde de silicium" and PM/REF 86285 as "Dioxyde de silicium silylé" without restrictions.

Arrêté du 9 Novembre 1994 relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boisson alimentaires, listed as "silice et silice silylée" on Annexe II, Section VI on Charges.

Arrêté du 25 Novembre 1992 relatif aux matériaux et objets en élastomères de silicone mis ou destinés à être mis au contact des denrées, produits et boisson alimentaires, listed as "silice et silice silylée" on Annexe I, Section I on Charges.

1.1.7 Germany

Directive 2008/39/EC was adopted by the *Siebzehnte Verordnung zur Änderung der Bedarfsgegenständeverordnung* of 23.09.2009, published in Bundesgesetzblatt I, 29.09.2009, p. 3130.

Silicon dioxide is furthermore listed on the following *BfR recommendations*:

- *XIV (Plastics dispersions) Part B* as protective colloid (*item 6*)
- *XXI (Commodities based on natural and synthetic rubber)* as filler for rubber goods of category 1 (*section 2.1.3.1.2.1*)
- *XXXVI (Paper and paper board for food contact)* as filler (*section A.III*)
- *XXXVII/1 (Cooking papers, hot filter papers and filter layers)* as auxiliary substance without restrictions (*item I.B.1*)
- *XXXVII/2 (Paper and paperboard for baking purposes)* as filler without restrictions (*item I.C.1*)
- *LII (Fillers for commodities made of plastic)* in section 1 as filler

Silicon dioxide, silanated is covered via the following entry in the *BfR recommendation LII (Fillers for commodities made of plastic)* in section 1 as filler:

"silicic acid, also in silylated form" with the following footnote: The treatment of silicic acids with silylating agents, e. g. dimethyl-dichlorosilane, serves the creation of silicic acids with hydrophobic properties. The agents are not detectable in the silylated silicic acids (detecting limit: 100 mg/kg).

There is also an entry in the *recommendation XXI (Commodities based on natural and synthetic rubber)* below fillers, which makes reference to the entry below item 1 in *recommendation LII*.

1.1.8 Italy

Directive 2004/19/EC adopted by *Decreto N. 227* of 04.05.2006, published in *Gazette Ufficiale N. 159* of 11.06.2006.

1.1.9 Spain

Directive 2005/79/EC adopted by *Orden SCO/3508/2006* of 10.11.2006, which modifies the attachments of *Real Decreto No. 118/2003* of 31.01.2003.

1.1.10 The Netherlands

Directive 2008/39/EC adopted by *Verpakkingen en Gebruiksartikelenbesluit*, last amended by *Regeling van 26 November 2008, Nr. VGP/PSL 2893617, houdende een wijziging van de Regeling Verpakkingen- en gebruiksartikelen (Warenwet) in verband met richtlijn Nr. 2008/39/EG* (Stct. 2008, 240, 10.12.2008).

Silicon dioxide is listed in *Verpakkingen- en Gebruiksartikelenbesluit (Warenwet) Bijlage Deel A* in

- *Hoofdstuk I (Plastics)* par. 2.3 a and 3.2
- *Hoofdstuk II (Paper and board)* par. 1 as filler
- *Hoofdstuk III (Rubbers)* par. 4 as filler
- *Hoofdstuk IV (Metals)* par. 2.2 as auxiliary
- *Hoofdstuk X (Surface coatings)* par. 3, 5, 6, 7, 11

Silicon dioxide, silanated is listed in *Verpakkingen- en Gebruiksartikelenbesluit (Warenwet) Bijlage Deel A* in

- *Hoofdstuk I (Plastics)* par. 2.3 a

1.1.11 Sweden

LIVSFS 2003:2 was last amended by *LIVSFS 2009:2* and includes the implementation of *Directive 2008/39/EC*.

1.1.12 UK

Directive 2008/39/EC adopted by *S.I. 2009/No. 205* (England), *S.I. 2009/No. 30* (Scotland), *S.I. 2009/No. 56* (Northern Ireland), *S.I. 2009/No. 481(W.49)* (Wales).

1.2 Switzerland

The approved substances of *Directive 2002/72/EC* have been taken over in the *Verordnung des EDI über Bedarfsgegenstände* from 23.11.2005, last amended 01.01.2009, in Annex I Part II.

2 List of Abbreviations

BfR:	German Bundesinstitut für Risikobewertung
EC:	European Commission
Ref. N.:	Packaging Materials Reference Number
QM:	Quantitative Maximum (maximum amount of a substance permissible in a food contact material such that the SML cannot be exceeded)
SML:	Specific Migration Limit
TDI:	Tolerable Daily Intake
ADI:	Acceptable Daily Intake

3 Disclaimer

This information is to our best present knowledge (state of knowledge according to last revision date) correct and given in good faith but without warranty. Our goal is to keep this information timely and accurate. However, we accept no responsibility or liability whatsoever with regard to the given information. The user of the information is kindly asked to recheck the topicality of the data especially in case the date of revision has been passed for more than 6 months.

*The manufacturer of any composition containing **Bindzil CC401** has the responsibility to ensure that the total composition complies with any food packaging regulation applicable to the specific end-use for which it is manufactured and complies with all specifically applicable restrictions.*

On behalf of Eka Chemicals AB:

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